AD_____

Award Number: W81XWH-07-1-0283

TITLE: PR064846: Predictors of Treatment Response to Fluoxetine in PTSD Following a Recent History of War Zone Stress Exposure

PRINCIPAL INVESTIGATOR: Paul B. Hicks

CONTRACTING ORGANIZATION: TEMPVA Research Group, Inc.
Temple, TX 76504

REPORT DATE: July 2008

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

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Paul B. Hicks

Email: paul.hicks@med.va.gov

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TEMPVA Research Group, Inc.
Temple, TX 76504

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14. ABSTRACT

Although selective serotonin reuptake inhibitors (SSRIs) are routinely prescribed for acute stress disorder and early PTSD and recommended in the VA-DoD best practice guidelines, the efficacy of SSRIs as an early intervention for PTSD in service members returning from war-zone duty has still not been determined. Consequently, this study was designed to conduct a controlled trial of fluoxetine as an early intervention for recently redeployed soldiers, as well as to develop methodologies for understanding the multiple risk factors that may predict outcome. The approval letter has been received from the Brooke Army Medical Center IRB, the regional IRB for the Carl R. Darnall Army Medical Center. The IRB has approved the protocol with the caveat that a CRADA must be completed between TEMPVA Research Group, Inc and the Carl R. Darnall Army Medical Center. The protocol has now also been approved by the Central Texas Veterans Health Care System IRB and the Research and Development Committee. The review by Kristen R. Katopol, MS, CIM, Human Subjects Protection Scientist (AMDEX Corp.) Human Research Protection Office (HRPO) Office of Research Protections (ORP) U.S. Army Medical Research and Materiel Command (USAMRMC) Fort Detrick is in progress. No subjects have been enrolled and will not be enrolled until final approval is obtained from USAMRMC.

15. SUBJECT TERMS
Fluoxetine, Posttraumatic Stress Disorder, Antidepressants

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
U	U	U	UU	37	19b. TELEPHONE NUMBER *(include area code)*

Table of Contents

Page

INTRODUCTION:

Although selective serotonin reuptake inhibitors (SSRIs) are routinely prescribed for acute stress disorder and early PTSD and recommended in the VA-DoD best practice guidelines, the efficacy of SSRIs as an early intervention for PTSD in service members returning from war-zone duty has still not been determined. Consequently, this study was designed to conduct a controlled trial of fluoxetine as an early intervention for recently redeployed soldiers, as well as to develop methodologies for understanding the multiple risk factors that may predict outcome. Fluoxetine was selected as the psychopharmacologic agent for this study because it is well tolerated, it has a very favorable cost-benefit advantage as a generic drug, and the fact that it is the only SSRI with at least preliminary studies demonstrating its efficacy in recent-onset, war-related PTSD. Studies focusing on targeting chronic combat-related PTSD with SSRIs have shown mixed results with some small open-label studies suggesting efficacy, while two controlled trials with Vietnam veterans were negative. In a recent study of survivors of war violence in Europe, Israel, and South Africa, fluoxetine was shown to significantly reduce PTSD symptoms. Because in all prior trials there is considerable variability of response to fluoxetine, we plan to examine several predictors of efficacy. We argue that the efficacy of SSRIs for recently redeployed soldiers at risk for chronic PTSD is moderated by multiple personal, deployment, and environmental factors. It is expected that not all subjects will respond to fluoxetine. For those that do not respond to fluoxetine alone, augmentation with either buspirone or buproprion will be offered based on their reasonable tolerability, low cost and the recent findings documenting their utility as adjunctive treatments for depression.

BODY:

The approval letter has been received from the Brooke Army Medical Center IRB, the regional IRB for the Carl R. Darnall Army Medical Center. The IRB has approved the protocol with the caveat that a CRADA must be completed between TEMPVA Research Group, Inc and the Carl R. Darnall Army Medical Center. The protocol has now also been approved by the Central Texas Veterans Health Care System IRB and the Research and Development Committee. The review by Kristen R. Katopol, MS, CIM, Human Subjects Protection Scientist (AMDEX Corp.) Human Research Protection Office (HRPO) Office of Research Protections (ORP) U.S. Army Medical Research and Materiel Command (USAMRMC) Fort Detrick is in progress. No subjects have been enrolled and will not be enrolled until final approval is obtained from USAMRMC.

Two research assistants have been hired. Both have master's degrees in counseling psychology and have considerable clinical experience, as well as some research experience. They are being trained on the administration of the psychological tests associated with this project and are developing the casebooks used in data collection until final approvals are given and recruitment begins. We have been assigned 3 offices and a testing area at the Carl R. Darnall Army Medical Center Resilience and Restoration Center, Bldg. 36009.

Credentialing and privileging of Drs. Peggy Pazzaglia and Paul Hicks at the Carl R. Darnall Army Medical Center has been completed. We have received assistance from the VA Office of Research and Development to place the CRADA in VA format. The CIRO at Ft. Sam Houston has agreed to accept the CRADA in VA format. The CRADA is being routed for signatures.

The first continuing review from the BAMC IRB has been approved (see Appendix).

PR064845 is now registered in ClinicalTrials.gov, No. NCT00633685.

Project Tasks:

Task 1: Submission of the Proposal to the IRBs

- The proposal must be approved by both the Brooke Army Medical Center IRB and the Central Texas Veterans Health Care System Human Subjects Subcommittee.
- **Completed**

Task 2: Recruitment and Training of Study Personnel

- Hire two master's prepared research assistants
- Training on recruitment procedures and research assessments (SCID, CAPS, etc.)
- **Training is in process, and will be completed in August 2008**

Task 3: Preparation of Over-Encapsulated Blinded Medications for the First Phase of the Clinical Trial

- Purchase of the fluoxetine and gelatin capsules from VA pharmacy suppliers (purchased each 3 months throughout the first 15 months of the study)
- Over-encapsulation of fluoxetine and empty gelatin capsules by CTVHCS Pharmacy staff
- Transfer of medications prepared by the CTVHCS Pharmacy directly to the Carl R. Darnall Medical Center Pharmacy
- **Will not be initiated until the CRADA is complete**

Task 4: Recruitment/Clinical Trial

- Enrollment of a minimum 20 subjects per month for 15 months
- Double-blind, placebo-controlled trial of fluoxetine + usual psychological care for 12 weeks
- Open-label extension of the fluoxetine trial for 20 weeks

Task 4: Data Collection and Transfer to the Boston VA National PTSD Research Center

Data will be stored on compact discs for storage

- Compact discs will be sent on a monthly basis to the National PTSD Research Center for database development
- The post-doctoral fellow working with Dr. Brett Litz will maintain the database under the oversight of Dr. Litz

Task 5: Data Analysis at the Boston VA National PTSD Research Center

KEY RESEARCH ACCOMPLISHMENTS: Not applicable

REPORTABLE OUTCOMES: Not applicable.

CONCLUSIONS: Not applicable.

REFERENCES: Not applicable.

APPENDICES:

Appendix A: BAMC IRB Approval letter
Appendix B: CTVHCS IRB Approval letter
Appendix C: CTVHCS R&D Committee Approval letter
Appendix D: CRADA

SUPPORTING DATA: Not applicable

MCHI-CI

NOV 2 6 2007

MEMORANDUM FOR **LTC Michael Adams, MS, Behavioral Health Division, Carl R. Darnall Army Medical Center, Ft Hood Texas**

SUBJECT: Institutional Review Board Approval Memo

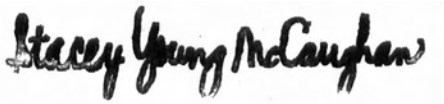
1. Your application for clinical investigation project **"Predictors of Treatment Response to Fluoxetine in PTSD following a Recent History of War Zone Stress Exposure"** was approved at the 4 April 2007 IRB and assigned work number **C.2007.145**.

2. To meet FDA and DoD requirements for maintaining records of participation in clinical investigation studies and documentation of informed consent, as the principal investigator, you must maintain the original **signed** informed consent.

3. As the principal investigator your responsibilities are as follows:

a. If authorized by the patient, ensure that a copy of the most current **IRB STAMPED** "Consent Form" is filed in the patient's health record/hospital chart.
b. Make a written entry in the patient's health record/health chart of enrollment in the study.
c. A change in the research plan must be reported to the DCI for submission to appropriate committees for approval prior to implementation.
d. If transferred or released from active duty, submit to the DCI the name of the individual who will continue the study.
e. If the study is terminated, submit a report to the DCI stating the study is terminated and the reason for termination.
f. If any serious adverse reactions occur during the study which were not expected, they must be reported to the Chief, DCI, within 24 hours.

4. An annual research progress report, to include a copy of the most current **IRB STAMPED** Consent Form must be submitted to my office NLT **1 March 2008** or upon completion, whichever comes first. Failure to comply could result in curtailment of funding for the project and/or termination.



STACEY YOUNG-McCAUGHAN
COL, AN
Chairman, IRB

DEPARTMENT OF THE ARMY
U.S. ARMY MEDICAL DEPARTMENT CENTER AND SCHOOL
CLINICAL INVESTIGATION REGULATORY OFFICE (CIRO)
ATTN: MCCS-GCI, 1608 STANLEY ROAD
FORT SAM HOUSTON, TEXAS 78234-5055

26 November 2007

MEMORANDUM FOR Commander, Brooke Army Medical Center, ATTN: MCHE-CI, Fort Sam Houston, TX, 78234

SUBJECT: Protocol Entitled "Predictors of Treatment Response to Fluoxetine in PTSD following a Recent History of War Zone Stress Exposure." Principal Investigator: LTC Michael Adams, MS. BAMC C.2007.145. CIRO 2007743.

1. The Clinical Investigation Regulatory Office (CIRO) has completed review of the above-referenced externally funded protocol and has determined that subject study complies with applicable human use protection regulations and may commence at Carl R. Darnall Army Medical Center.

2. A Cooperative Research and Development Agreement (CRADA) with TEMPVA Research Group, Inc. in support of the study is planned but has not yet been received by CIRO. Please note that extramural resources may not be accepted/utilized until an approved CRADA is in place.

3. Point of contact is Ms. Christina Jones at 221-9322.

JAMES M. LAMIELL
Colonel, MC
Chief, Clinical Investigation
Regulatory Office

MCHE-CI 17 January 2008

MEMORANDUM FOR LTC Michael Adams, Department of Behavioral Medicine, Behavioral Health Service, Carl R. Darnall Medical Center, Ft. Hood, TX

SUBJECT: Protocol Assessment

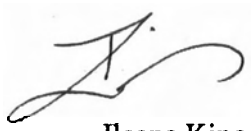
1. On 17 January 2008, the Department of Clinical Investigation performed an assessment of the protocol titled **"Predictors of Treatment Response to Fluoxetine in PTSD Following A Recent History of War Zone Stress Exposure"** (C.2007.145).

2. The procedures, documentation and mechanisms to ensure confidentiality, security, data management and analysis of protocol were discussed and determined to be appropriate.

3. The files pertaining to the protocol and PHI collected were stored in a locked cabinet and office.

4. The protocol is ongoing. No participants have been enrolled. All documents were available for review and are the most currently approved versions.

5. No additional action is warranted at this time. Thank you for your assistance today. For any questions or concerns, I can be reached to 210-916-2000.



Ileana King
HIPAA Research Compliance & Quality Coordinator
Department of Clinical Investigation

MCHE-CI 05 March 2008

MEMORANDUM FOR **LTC Michael Adams, PhD**, Department of Behavioral Medicine, Behavioral Health Service, Brooke Army Medical Center, Ft. Sam Houston, TX

SUBJECT: Continuing Review of the protocol entitled: **"Predictors of Treatment Response to Fluoxetine in PTSD Following A Recent History of War Zone Stress Exposure" C.2007.145**

1. The BAMC Institutional Review Board met on 05 March 2008. The IRB performed a continuing review on the protocol listed above. The IRB approved the continuation of the protocol.

2. The next scheduled continuing review for this protocol will be February 2009.

3. POC is the undersigned at (210) 916-4495.

THOMAS C. JEFFERSON
COL, MC
Chairman, IRB

/cd

Department of Veterans Affairs

Memorandum

Date: June 11, 2008

From: Chairperson, Institutional Review Board (IRB) (151)

Subj: Review of Amended document

To: Paul B. Hicks, M.D. (151)

1. The IRB members reviewed your memorandum dated March 19, 2008, subj: Predictors of Treatment Response to Fluoxetine in PTSD Following a Recent History of War Zone Stress Exposure; the revised informed consent form dated March 19, 2008; and the Central Texas Veterans Health Care System (CTVHCS) Authorization to use and Disclose Protected Health Information for Research form, for your study entitled, "Predictors of Treatment Response to Fluoxetine in PTSD Following A Recent History of War Zone Stress Exposure," at the March 24, 2008, meeting. The members approved the study contingent upon specified changes being incorporated and submitted for review and approval of the Chairs of the IRB and R&D.

2. The requested items were received, reviewed, and approved with your memorandum dated June 10, 2008.

2. The approval period is from **March 24, 2008**, to **March 23, 2009**. Approval is given to the study for no more than **300** human subjects at the Carl R. Darnell Army Medical Center as outlined in the study packet.

3. After receipt of the final approval letter from the research office, participants may be entered into this study with the implicit understanding that all assurances given to the Subcommittee on Human Studies regarding the execution of this study are carried out. Failure to do so will result in revocation of this authorization.

4. You are reminded that informed consent must be obtained by the principal investigator and/or research team members who have been approved by the IRB to obtain informed consent from subjects prior to initiation of any study procedures. The informed consent must be signed, witnessed, and copies of the consent form (VA Form 10-1086) must be given to the subject and placed in the patient's medical record, and in a separate study file maintained in your office or laboratory. These files must be maintained for a minimum of five years following the completion of the research and will doubtless be subjected to review by this Subcommittee and by other federal agencies. In addition, any protocols involving human subjects in radiation, radioisotopes, or nuclear medicine will be retained indefinitely.

5. Any unanticipated problems or serious adverse events of this study must be reported in writing by the investigator to this Subcommittee within 24 hours of the occurrence, whether or not these are attributed to the research project itself or to unrelated factors.

In addition, adverse reactions to drugs must be reported to the Committee of Pharmacy and Therapeutics. If there is any question please contact the Research Department.

6. Any modifications to the study protocol or to the consent form must be reviewed by the IRB. Completion or cessation of this study should be reported to this Subcommittee as soon as possible. If modifications of any kind are put into place without IRB approval, this is a violation and non-compliance with federal and VHA regulations and policies.

7. Your study will be subjected to further continuing review on **March 23, 2009.** Request the continuing review submission forms be submitted to this office on **January 14, 2009,** for review by the IRB. If the protocol or consent form is modified in any way or discontinued for any reason before the next continuing review, please notify the Subcommittee.

8. Investigators are reminded that they are personally responsible for the careful, thoughtful execution of studies involving human subjects. Conscious disregard of subjects' rights as outlined in the consent form or failure to comply with all safeguards listed in the protocol will be met with severe sanctions. Confidentiality of human subject identity/personal data is mandatory.

9. The Subcommittee wishes you success with this investigation.

10. You may begin to use the attached consent form (dated April 11, 2008).

11. If additional information is needed please call Lorrie Thomas, Program Specialist/OA, at extension 41974.

John W. Klocek Ph.D.
John Klocek, Ph.D.

Attachments

Department of Veterans Affairs

Memorandum

Date: June 16, 2008

From: Chairperson, Research and Development (R&D) Committee

Subj: Protocol Review

To: Paul B. Hicks, M.D. (151)

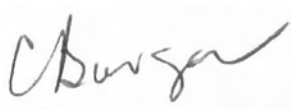
1. The R&D members reviewed your application, protocol, Brooke Army Medical Center (BAMC)/Carl R. Darnall Army Medical Center (CRDAMC) informed consent, and the amended documents submitted with memorandum dated March 19, 2008, for the study entitled, **"Predictors of Treatment Response to Fluoxetine in PTSD Following A Recent History of War Zone Stress Exposure,"** at the **April 1, 2008,** meeting. The above study is approved contingent upon items requested by the Institutional Review Board (IRB) at the March 24, 2008, meeting. All items were received, reviewed, and approved by the Chair of the IRB.

IRB	March 24, 2008
Privacy Act Officer	March 24, 2008
Subcommittee on Research Safety a Subcommittee of the R&D Committee	N/A
R&D Committee	April 1, 2008
IACUC Final Approval	N/A
Medication Use Committee	N/A

2. Your study will be subjected to further continuing review by the R&D Committee on **March 24, 2009.** Request the updated forms (project data sheet and abstract) be submitted to this office on **January 27, 2009,** for review by the R&D Committee.

3. If you have any questions or concerns, please do not hesitate to contact Lorrie Thomas, Program Specialist/OA, at extension 41974.

4. You may ~~being~~ begin the above study.



Charles G. Burgar, M.D.

COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT BETWEEN CLINICAL INVESTIGATION REGULATORY OFFICE, U.S. ARMY MEDICAL DEPARTMENT CENTER AND SCHOOL

AND

TEMPVA RESEARCH GROUP, INC.

AND

DEPARTMENT OF VETERANS AFFAIRS, BOSTON AND CENTRAL TEXAS VETERANS HEALTH CARE SYSTEMS

AND

BROOKE ARMY MEDICAL CENTER

The Clinical Investigation Regulatory Office, U.S. Army Medical Department Center and School (hereinafter "Federal Laboratory" when used individually), and **TEMPVA RESEARCH GROUP, INC.** (hereinafter "Collaborating Party") enter into this Cooperative Research and Development Agreement (CRADA) for performing the medical research, development, test, and/or evaluation (RDTE) work. Department of Veterans Affairs (VA) and Brooke Army Medical Center (BAMC) are also the other federal parties to this agreement. The Federal Laboratory in addition VA and BAMC are hereafter referred to as "Federal Parties" collectively. Roles and responsibilities of each party is identified in the Statement of Work (SOW) and attached as an Appendix.

Article 1
General

1.1. Authority. This CRADA is entered into pursuant to the Stevenson-Wydler Technology Innovation Act of 1980 as amended by the Federal Technology Transfer Act (Title 15, United States Code (U.S.C.) §§3701 et seq.), which permits directors of Federal laboratories to enter into cooperative research and development agreements and intellectual property licenses for intellectual property owned by or assigned to the United States Government. This is not a procurement contract, grant, or cooperative

agreement as those terms are used in 31 U.S.C. §§6303, 6304, and 6305.

1.2. Entire Agreement. This CRADA includes the attached SOW (Appendix) and together they constitute a single, entire document hereinafter referred to as the "Agreement."

1.3. Purpose. The purpose of this Agreement is share resources and information towards the successful completion of the RDTE project (the "Study"). The medical objective of the Study is described in the SOW.

1.4. Statement of Work. The RDTE project, which is described in the SOW, will be conducted under a clinical research protocol which has been reviewed by the appropriate Institutional Review Board in accordance with Army Regulation 40-38, Clinical Investigation. The SOW incorporates all of the terms and provisions of these Articles by reference. In cases of apparent conflict between the terms and provisions of the SOW and these Articles, the terms and provisions of the Articles shall control.

1.5. Consideration. The Federal Parties and the Collaborating Party agree that they are entering into this Agreement for the mutual benefit of each Party. The Federal Parties and the Collaborating Party will cooperate in support of the clinical investigation protocol specified in the SOW. The RDTE project entered into under this Agreement will benefit the Federal Parties by providing valuable research experience for the Principal Investigator and medical residents involved and by providing valuable access to new drugs and medical devices for the medical treatment of Army patients. In addition, patients involved in the RDTE project may benefit directly from the medical treatment received and all medical patients will potentially benefit from the knowledge gained as a result of the RDTE project. The Collaborating Party will also benefit from the medical knowledge gained, through the evaluation of the clinical characteristics of emerging health technologies that will be applied for the public good.

1.6. Principal Investigator. The RDTE project conducted under the SOW will be supervised by one or more Principal Investigators named therein. The Principal Investigator may be changed for good cause by written notification to the other Party.

1.7. Federal Parties' Representative. The person signing this Agreement on behalf of the Federal Parties represents that he or she has the authority to enter into this Agreement. Notwithstanding this authority, the Secretary of the Army has reserved to the Assistant Secretary of the Army (Research, Development, and Acquisition) the authority provided by 15 U.S.C.

§3710a(c)(5)(A) to disapprove or require modification of this Agreement within 30 days of the date it is presented to the Assistant Secretary. If the Assistant Secretary disapproves this Agreement, the Agreement is null and void. If the Assistant Secretary requires modification of this Agreement, the Collaborating Party shall have 30 days from notification of such action to ratify the modification(s) or terminate this Agreement.

1.8. Collaborating Party Representative. The person signing this Agreement on behalf of the Collaborating Party represents that he or she has the authority to bind the Collaborating Party to the terms of this Agreement and the execution and delivery of this Agreement does not contravene any material provision of, or constitute a material default under, any material agreement binding on the Collaborating Party or any valid order of any court, any regulatory agency, or other body having authority to which the Collaborating Party is subject.

Article 2
Definitions

2.1. "Agreement" refers to the entire CRADA including the SOW.

2.2. "Adverse Drug Experience" means an adverse event as defined under 21 C.F.R. §310.305, Records and Reports Concerning Adverse Drug Experience, and other applicable Federal Regulations.

2.4. "Clinical Brochure" means a document containing all the relevant information about a drug, including animal screening, preclinical toxicology, and detailed pharmaceutical data. Also included, if available, is a summary of current knowledge about pharmacology, mechanism of action, and a full description of the clinical toxicities.

2.5. "Collaborating Party" means the person(s), intermediary(ies), or entity(ies), including medical and pharmaceutical companies, sponsoring a research project pursuant to this Agreement.

2.6. "Computer software" or "software" means computer programs, source code, source code listings, object code listings, designs, details, algorithms, processes, flow charts, formulae, and related material that would enable the software to be reproduced, recreated, or recompiled. Computer software does not include computer databases or computer software documentation.

2.7. "FDA" means the Food and Drug Administration, Department of Health and Human Services.

2.8. "Federal Laboratory" means the Clinical Investigation Regulatory Office, U.S. Army Medical Department Center & School, Fort Sam Houston, which has been designated by the Secretary of Army as a Federal laboratory.

2.9. "Government" means the United States of America and the agencies thereof.

2.10. "Government purpose" means any activity in which the Government is a Party, including cooperative agreements with international or multinational defense organizations, or sales or transfers by the Government to foreign governments or international organizations, and competitive procurements. Government purpose does not include for commercial purposes.

2.11. "Invention" means any invention or discovery which is or may be patentable or otherwise protected under Title 35 of the United States Code or any novel variety of plant which is or may be protected under the Plant Variety Protection Act (7 U.S.C. §§2321 et seq.).

2.12. "Made" when used in conjunction with any invention means the conception or first actual reduction to practice of such invention.

2.13. "Party" or "Parties" refers to the Federal Laboratory, the Intermediary, or the Collaborating Party or all (in singular or plural usage as indicated by the context).

2.14. "Principal Investigator" means an individual who actually conducts a clinical investigation (i.e. under whose immediate direction a drug is administered or dispensed to a subject). In the event an investigation is conducted by a team of individuals, the Principal Investigator is the responsible leader of the team. "Subinvestigator" includes any other individual member of that team (21 C.F.R. §312.3).

2.15. "Proprietary information" means information which embodies trade secrets or which is confidential technical, business, or financial information provided that such information:

a. is not generally known, or is not available from other sources without obligations concerning its confidentiality;

b. has not been made available by the owners to others without obligation concerning its confidentiality;

c. is not described in an issued patent or a published copyrighted work or is not otherwise available to the public without obligation concerning its confidentiality;

d. can be withheld from disclosure under 15 U.S.C. §3710a(c)(7)(A)&(B) and the Freedom of Information Act, 5 U.S.C. §552 et seq; and

e. is identified as such by labels or markings designating the information as proprietary.

2.16. "Raw Data" means the primary quantitative and empirical data first collected by the intramural and extramural investigators from experiments and clinical trials conducted under the scope of this Agreement.

2.17. "Subject data" means any technical data first produced in the performance of work under this Agreement.

2.18. "Subject Invention" means any invention conceived or first actually reduced to practice in the performance of work under this Agreement.

2.19. "Technical data" means recorded information, regardless of the form or method of the recording, of a scientific or technical nature (including computer software documentation and databases). The term does not include computer software or data incidental to the administration of this Agreement, such as financial or management information.

Article 3
Cooperative Research

3.1. Review of Work. Periodic conferences may be held between the Parties for the purpose of reviewing the progress of the cooperative effort. It is understood that the nature of this cooperative effort is such that completion within the period of performance specified or within the resources allotted cannot be guaranteed. Accordingly, it is agreed that all cooperative research and development activities performed by either Party are to be performed on a best efforts basis.

3.2. Changes. If at any time the Principal Investigator, a Collaborating Party, or the Federal Parties determines that the research data dictates a substantial change in the direction of the work, he or she shall promptly notify the Parties, and the Parties shall make a good faith effort to agree to any necessary changes to the SOW consistent with the basic scope of research.

3.3. Assignment of Personnel. If the SOW contemplates the assignment of one Party's personnel to the other Party's facilities, then the employees shall remain employees of the

assigning Party and will not be considered as employees of the other Party for any purpose, including but not limited to any requirements to provide workers' compensation, payment of salary or other benefits, or withholding of taxes. Assigned personnel will observe the other Party's security, safety, health, and environmental facility regulations. Assigned personnel can be denied access or removed by the other Party from its facilities at its discretion. Collaborating Party personnel assigned to Federal Parties will work under the direction of the Principal Investigator only. That direction will be limited to matters within the scope of the actual research and will not extend to any matters that are normally encompassed by the employer-employee relationship. For example, the Collaborating Party is responsible for determining the working hours of its assigned personnel.

Article 4
Reports

4.1. Progress Reports. As provided in the SOW, the Parties will prepare and exchange written reports, in a timely manner, on the progress of their work, results obtained, problems encountered, and recommendations for further research and development. To the extent reasonable, further detail concerning the contents of the reports shall be provided upon request, if necessary for the other Party to fully understand the results achieved. At a minimum, the Principal Investigator will submit annual progress reports to the Parties.

4.2. Final Report. As provided in the SOW, the Parties will prepare and exchange a final report at the completion of the cooperative effort performed under this Agreement, on the progress of their work, results obtained, problems encountered, and recommendations for further research and development. To the extent reasonable, further detail concerning the contents of the report(s) shall be provided upon request if necessary for the other Party to fully understand the results achieved.

4.3. Adverse Drug Experiences, Annual Reports, Other Investigational New Drug Data. The Federal Parties will provide the Collaborating Party with copies of all adverse drug experience reports. The Federal Parties shall establish and maintain records and make reports to the FDA for the following Adverse Drug Experiences: (1) all serious, unexpected adverse drug experiences, (2) any significant increase in the frequency of serious unexpected adverse drug experiences, and (3) any significant increase in the frequency of therapeutic failure.

Article 5
Transfer of Funds

5.1. Payment Schedule. The payment schedule, described in the SOW, is subject to modification by mutual consent of all Parties in the event unforeseen circumstances arise which delay initiation of this project, including delays due to insufficient volunteer enrollment, actions from responsible review or regulatory authorities, lack of equipment, malfunctions, or insufficient support personnel. In the event of cancellation or termination of a research project, the Collaborating Party shall not be responsible for payments beyond such cancellation or termination date except for payments which have accrued prior to said date and as yet remain unpaid. The U.S. Government shall not reimburse the Collaborating Party for its expenditures prior to cancellation or termination of the research project.

5.2. Federal Party. Under this Agreement no Federal Party shall provide any funds to any other Party. The Federal Parties shall contribute equipment, material and services toward the cooperative research and development effort as set forth in the SOW.

5.3. Collaborating Party. The Collaborating Party shall transfer funds and other resources to the BAMCfor the performance of research and development as set forth in the SOW.

5.4. Salaries and Travel. Unless otherwise provided in the SOW, each Party shall provide financial support to its respective personnel in the performance of this Agreement, including salary, reimbursement for travel, and other expenses as appropriate.

5.5. Accounting Records. BAMC and the Collaborating Party shall each maintain separate and distinct current accounts, records, and other evidence supporting all its expenditures under this Agreement. The accounts and records of BAMC which are relevant to the conduct of this project shall be available for reasonable inspection and copying by the Collaborating Party or its authorized representative.

Article 6
Personal and Real Property

6.1. Personal Property. Any tangible personal property provided by a Party during the performance of this Agreement shall remain the personal property of the Party providing it, unless otherwise agreed in the SOW. Property provided by a Party to another Party may only be used for the performance of the cooperative effort under this Agreement, unless otherwise agreed in the SOW. Government property may be repaired or modified by the Collaborating Party at its expense only after obtaining the written approval of the Federal Parties. Any repair or

modification of the property shall not affect the title of the Government. The Federal Parties makes no warranty, express or implied, with respect to property contributed or loaned by it. Upon completion of the cooperative effort performed under this Agreement, each Party shall immediately account for the property in its possession and return, at its expense, all property belonging to the other Party in the condition in which it was received, normal wear and tear excepted. Any disposal of property shall be in accordance with applicable Federal, State, and local environmental laws and regulations.

6.2. Real Property. Any real property made available for use by a Party to another Party for the performance of this Agreement shall remain the property of the Party providing it. Any use of such property shall be in accordance with all applicable Federal, State, and local laws and regulations to include environmental laws and regulations.

Article 7
Patents

Each Party shall promptly disclose in writing to the other Party Subject Inventions made by its employees or subcontractors in sufficient detail to enable someone with skill in the art to make and use the inventions. Parties shall coordinate patent filing, prosecution, and patent maintenance payments with their respective patent counsels.

Article 8
Proprietary and Protected Information

8.1. Exchange of Data. The Parties agree to exchange all subject data produced in the course of the performance of this Agreement. All information or data exchanged between the Parties in the course of, or in contemplation of, this Agreement may be used and disseminated without restriction by the Parties for any purpose unless the data or information is proprietary or otherwise protected as provided in paragraph 10.2 or Article 8.

8.2. Proprietary and Protected Information.

8.2.1. Form. Proprietary or protected information may be disclosed to another Party orally, electronically, visually, in writing, or in any other tangible or intangible form. If it is initially disclosed in a nonfixed media, then the Party disclosing the data must furnish the other Party with the information in a fixed media with appropriate marking within ten days of its initial disclosure. Failure to furnish the fixed

media within ten days or to prominently mark the information as proprietary or otherwise protected will not automatically result in the loss of the information's protected status, but will excuse any Party's unauthorized disclosure or use of the information caused by the failure to meet the ten-day suspense to properly mark the information.

8.2.6. FDA Documents. If this Agreement involves a product regulated by the FDA, then the Collaborating Party or the Federal Parties, as appropriate, may file any required documentation with the FDA. In addition, the Parties authorize and consent to allow each other or its contractor or agent access to, or to cross-reference, any documents filed with the FDA related to the product.

10.2.7. Standard of Care. Each Party is obligated to use reasonable care in the protection of proprietary and protected information.

Article 9
Prepublication Review

9.1. Publication. The Parties anticipate that their employees may wish to publish technical developments and/or research findings made under this Agreement. Each Party shall submit to the other Party prior to publication or other public disclosure, any proposed publication or disclosure pertaining to work under this Agreement. The other Party shall provide a written response within 30 days either objecting or not objecting to the proposed publication or public disclosure. The proposed publication or public disclosure shall not be deemed objectionable unless the proposed publication contains proprietary information, protected information, or material that would create potential statutory bars to the filing of U.S. or corresponding foreign patent applications, or for any other reasonable basis.

9.2. Protection of Proprietary Rights. If requested in writing by either Party, the Collaborating Party, the Principal Investigator, and/or the Federal Parties shall withhold such submission for publication an additional 60 days to allow for filing a patent application or taking such measures as the requester deems appropriate to establish and preserve its proprietary rights in the information in the manuscript or disclosure.

Article 10
Export Control

10.1. Compliance. The Parties understand that information and technology resulting from the performance of this Agreement may be subject to export control laws and regulations, and each Party is responsible for its own compliance with such laws and regulations. Nothing in this Agreement waives any such statutory or regulatory requirement.

Article 11
Warranty

11.1. **NO WARRANTY. EXCEPT AS SPECIFICALLY STATED ELSEWHERE IN THIS AGREEMENT OR THE SOW, THE PARTIES MAKE NO EXPRESS OR IMPLIED WARRANTY AS TO THE CONDITIONS OF THE RESEARCH, INVENTIONS, OR TECHNICAL DATA, OR PRODUCTS EXCHANGED, MADE, OR DEVELOPED UNDER THIS AGREEMENT, OR THE OWNERSHIP, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE, TECHNICAL FEASIBILITY, OR FREEDOM FROM**

INFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS OF THE RESEARCH, INVENTIONS, TECHNICAL DATA, OR PRODUCTS.

Article 12
Force Majeure

12.1. Force Majeure Events. Neither Party shall be liable for any unforeseen event beyond its reasonable control not caused by the fault or negligence of such Party, which causes such Party to be unable to perform its obligations under this Agreement and which it has been unable to overcome by the exercise of due diligence. Such unforeseen events include, but are not limited to, fire, storm, flood, earthquake or other natural catastrophes, accidents, acts of civil disturbance or disobedience, war, rebellion, insurrection, labor strikes or disputes, compliance with any laws, requirements, rules, regulations, or orders of any governmental authority or instrumentality thereof, sabotage, invasion, quarantine, and embargoes.

12.2. Best Efforts. The excused Party shall use its best efforts to resume performance as quickly as possible and shall suspend performance for only such period as is reasonably necessary as a result of the force majeure event.

Article 13
Severability

13.1. Contrary to Law. Any provision of this Agreement, to include the SOW, that is prohibited by applicable law is void, but the remaining provisions shall survive.

Article 14
Termination

14.1. Mutual Consent. The Parties may elect to terminate this Agreement, or portions thereof, at any time by mutual consent.

14.2. Unilateral Action. Either Party may unilaterally terminate this Agreement at any time by giving the other Party written notice, not less than 30 days prior to the desired termination date.

14.3. Termination Costs. Unless otherwise specifically provided in this Agreement, each Party shall be responsible for all of the costs for which it bears responsibility under this Agreement which have been incurred through the effective date of

termination. Each Party shall be solely responsible for any costs it incurs after the effective date of termination.

14.4. Continuing Obligations. In the event of termination, the Parties shall specify the disposition of all property, patents, and other results of work accomplished or in progress under this Agreement, when such disposition is not otherwise specified in this Agreement. All obligations under this Agreement to safeguard proprietary and other protected information and relating to rights in intellectual property or technical data shall survive any termination of this Agreement. The termination of this Agreement shall not affect the rights and obligations of the Parties accrued prior to the effective date of termination.

Article 15
Disputes

15.1. Resolution Procedures. The Parties recognize that disputes arising under this Agreement are best resolved at the working level. Parties are encouraged to be imaginative in designing mechanisms and procedures to resolve disputes at the lowest level possible as soon as practicable. The Parties agree to use their best efforts to resolve any dispute amongst themselves. Any dispute arising under this Agreement which is not disposed of by agreement of the Parties at the working level shall be submitted jointly to the signatories of this Agreement or their successors or their designees for resolution.

Article 16
Modifications

16.1. Modifications. If either Party desires to modify this Agreement, the Parties, upon reasonable notice of the proposed modification by the Party desiring the change, shall confer in good faith to determine the desirability of such modification. Any resulting modification shall not be effective until a written amendment is signed by the duly authorized representatives of the Parties. Any material modification of this Agreement is subject to the authority of the Assistant Secretary of the Army (Research, Development, and Acquisition) as provided in paragraph 1.7 of this Agreement to disapprove or require modification within 30 days of the date it is presented to the Assistant Secretary.

Article 17
Interpretation

17.1. Entire Agreement. This Agreement includes Articles 1 - 25 and the SOW (Appendix). Together, they constitute the entire agreement between the Parties with respect to the subject matter hereof and all prior representations or agreements relating hereto have been merged into the documents and are superseded in totality by this Agreement.

17.2. Precedence. In the event of a conflict between the terms and provisions of the SOW and the terms and provisions in the Articles, the terms and provisions in the Articles shall control.

Article 18
Notices

18.1. Notices. All notices, pertaining to or required by this Agreement, shall be in writing and shall be delivered by hand or sent by certified mail, return receipt requested, express mail, or private delivery service addressed as specified below. Any Party may change such address by written notice given to the other Party in the manner set forth.

Mailing Address of Federal Parties:

Clinical Investigation Regulatory Office (ATTN: MCCS-GCI)
U.S. Army Medical Department Center & School
Bldg. 2268, 1608 Stanley Road (Stop 55)
Fort Sam Houston, TX 78234-6125

Department of Clinical Investigation, ATTN: MCHE-CI
Brooke Army Medical Center
3400 Rawley E. Chambers Ave., Suite A
Fort Sam Houston, TX 78234-6315
Phone: (210) 916-0607
FAX: (210) 916-0927

ACOS, Research
Central Texas Veterans Health Care System (151)
1901 S. Veterans Memorial Dr.
Temple, TX 76504
Phone: (254) 743-2643
FAX: (254) 743-0555

Add Boston VA contact info:

Mailing Address of Collaborating Party:

TEMPVA RESEARCH GROUP, INC.
1901 S. Veterans Memorial Dr.

Temple, TX 76504

20.2 Waiver. None of the provisions of this Agreement shall be considered waived by any Party unless such waiver is given in writing to the other Party. The failure of a Party to insist upon strict performance of any of the terms and conditions hereof, or failure or delay to exercise any rights provided herein or by law, shall not be deemed a waiver of any right of any Party hereto.

Article 21
Nonassignment

21.1. Nonassignment. This Agreement may not be assigned or otherwise transferred by either Party without the prior written consent of the other Party.

Article 22
Officials Not To Benefit

22.1. Officials Not to Benefit. No member of Congress shall be admitted to any share or part of this Agreement, or to any benefit that may arise therefrom; but this provision shall not be construed to extend to this Agreement if made with a corporation for its general benefit.

Article 23
Endorsements

23.1. No Endorsements. By entering into this Agreement, Federal Parties do not directly or indirectly endorse any product or service provided by the Collaborating Party, its successors, assignees, or licensees. The Collaborating Party shall not in any way imply this Agreement is an endorsement by the Government of any such product or service.

23.2. Use of Name. The Collaborating Party may use, refer to, and disseminate reprints of scientific, medical, and other published articles which disclose the name of the Federal Parties consistent with U.S. copyright laws, provided such use does not constitute, or imply, an endorsement of any commercial product or service by the U.S. Government. The Collaborating Party shall take every step possible to ensure that references to the articles are accurate, and shall explicitly state that any such reference does not claim, infer, or imply an endorsement or recommendation of the product or service by the U.S. Government.

The Collaborating Party shall not use the name of the Principal Investigator or the Federal Parties in any advertising, packaging, or promotional material in connection with a product or service. The Principal Investigator and the Federal Parties shall not use the name of the Collaborating Party in any publication or presentation regarding the Study except with the written permission of the Collaborating Party or as may be required by law.

Article 24
Governing Law

24.1. The construction, validity, performance, and effect of this Agreement for all purposes shall be governed by the laws applicable to the Government of the United States.

Article 25
Duration of Agreement

25.1. Effective Data. This Agreement will be effective upon the date that the last Party signs this Agreement.

25.2. Duration. It is mutually recognized by the Parties that the objectives to be attained by this Agreement cannot be rigidly defined in advance and that projected milestones are subject to adjustment by mutual agreement of the Parties. Notwithstanding, this Agreement will not extend beyond the latest period of time stated in the SOW executed under this Agreement.

25.3. Continuing Obligations. All obligations under this Agreement to safeguard proprietary and other protected information and relating to publication, liability, rights in intellectual property or technical data existing at the termination or expiration of this Agreement shall survive the termination/expiration of this Agreement.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as follows:

For the Federal Laboratory:

BY: _____ DATE: _____

Colonel James M. Lamiell, Medical Corps
Chief, Clinical Investigation Regulatory Office
U.S. Army Medical Department Center & School

1608 Stanley Road Bldg. 2268
Fort Sam Houston, Texas 78234-6125
Phone Number: (210) 221-2511; FAX (210) 295-0244

For **TEMPVA RESEARCH GROUP, INC.** (Collaborating Party):

BY: _____ DATE: _____

Debbie Boyd
Executive Director
1901 S. Veterans Memorial Dr.
Temple, TX 76504
Phone Number: 254-743-2295 FAX: 254-743-0155

Need signature section for BAMC and VA:

APPENDIX

STATEMENT OF WORK

A. IDENTIFICATION.

A.1. Subject Category: Medicine & Biology (Clinical Medicine), Code 57E, Title: " Predictors of Treatment Response to Fluoxetine in PTSD Following a Recent History of War Zone Stress Exposure." Short Title: "Fluoxetine in the Treatment of PTSD".

A.2. The Clinical Investigation Regulatory Office (Federal Laboratory) and TEMPVA RESEARCH GROUP, INC. (Collaborating Party) desire to collaborate in research and development and will cooperate in support of the clinical investigation protocol at Brooke Army Medical Center (BAMC) entitled, " Predictors of Treatment Response to Fluoxetine in PTSD Following a Recent History of War Zone Stress Exposure," (the "Study") by Michael Adams, Ph.D. (Principal Investigator), serving at the Carl R. Darnall Army Medical Center Army Medical Center, 36000 Darnall Loop Fort Hood, Texas 76544-4752, acting under the guidance of the Federal Laboratory.

A.3. This Statement of Work (SOW) is executed under authority of the Stevenson-Wydler Technology Innovation Act of 1980 as amended by the Federal Technology Transfer Act (15 U.S.C. §§3701 et seq.) and hereby incorporates all of the terms and provisions of the CRADA. Together, the CRADA and this SOW constitute the entire Agreement of the Parties. In the case of a conflict between the provisions of this SOW and the CRADA, the terms and provisions of the latter shall control.

B. PURPOSE.

B.1. Whereas, the Federal Parties and the Collaborating Party are entering into this Agreement for the mutual benefit of each Party. This joint research project will benefit the Collaborating Party by providing preliminary treatments for PTSD in future veterans. The project will benefit the Federal Parties by providing valuable research experience for the medical residents of the teaching program involved. In addition, patients at Carl R. Darnall Army Medical Center with Posttraumatic Stress Disorder will benefit through facilitating studies of the use of fluoxetine to treat PTSD in active duty soldiers.

C. MEDICAL OBJECTIVE.

C.1. This project will attempt to demonstrate the efficacy of fluoxetine for the treatment of Posttraumatic Stress Disorder in soldiers with a recent history of war zone stress exposure.

D. DESCRIPTION OF WORK.

D.1. Predictors of Treatment Response to Fluoxetine in PTSD Following a Recent History of War Zone Stress Exposure

Project Tasks:
Task 1: Submission of the Proposal to the IRBs

- The proposal must be approved by both the Brooke Army Medical Center IRB and the Central Texas Veterans Health Care System Human Subjects Subcommittee.

Task 2: Recruitment and Training of Study Personnel

- Hire two master's prepared research assistants
- Training on recruitment procedures and research assessments (SCID, CAPS, etc.)

Task 3: Preparation of Over-Encapsulated Blinded Medications for the First Phase of the Clinical Trial

- Purchase of the fluoxetine and gelatin capsules from VA pharmacy suppliers (purchased each 3 months throughout the first 15 months of the study)
- Over-encapsulation of fluoxetine and empty gelatin capsules by CTVHCS Pharmacy staff
- Transfer of medications prepared by the CTVHCS Pharmacy directly to the Carl R. Darnall Medical Center Pharmacy

Task 4: Recruitment/Clinical Trial

- Enrollment of a minimum 20 subjects per month for 15 months
- Double-blind, placebo-controlled trial of fluoxetine + usual psychological care for 12 weeks
- Open-label extension of the fluoxetine trial for 20 weeks

Task 4: Data Collection and Transfer to the Boston VA National PTSD Research Center

- Data will be stored on compact discs for storage
- Compact discs will be sent on a monthly basis to the National PTSD Research Center for database development
- The post-doctoral fellow working with Dr. Brett Litz will maintain the database under the oversight of Dr. Litz

Task 5: Data Analysis at the Boston VA National PTSD Research Center

D.3. All performance under this SOW will cease at either the completion of all work, unilateral or mutual termination, or June 30, 2011, whichever occurs first.

E. RESOURCES PROVIDED BY COLLABORATING PARTY. The Collaborating Party will furnish the following research resources:

E.1. Investigational Drugs: Not applicable

E.2. Approved Drugs: Fluoxetine
Bupropion SR
Buspirone

E.3. Approved Devices: Not applicable

E.4. Consumable Supplies: 600 Vacutainer Purple top tubes for blood draws.

E.5. Capital Equipment: Not applicable

E.6. Assay Results: Not applicable

E.7. Services of Personnel: Dispensing of study medications by the Carl R. Darnall Army Medical Center Pharmacy.

E.8. Loan of Equipment: Three desktop computers

E.9. Travel: Not applicable

E.10. Funds: Supplies will be purchased by the Central Texas Veterans Health Care System with TEMPVA Research Group, Inc. funds and transferred to Carl R. Darnall Army Medical Center for immediate use. No funds will be transferred.

E.11. Other: IRB fee of $1,000.00 and CRADA administrative processing fee of $500.00 for CRADAs less than $10,000.00, or 5% of the value of any CRADA more than $10,000.00, excluding donated pharmaceuticals.

E.12. The above are hereinafter referred to as "Resources." Information relating to them, including data generated under this Agreement, is hereinafter referred to as "Information." Brooke Army Medical Center agrees that the Resources and Information will be used for research and clinical purposes only as provided in this Agreement. The Resources shall not be sold, offered for

sale, used for commercial purposes, or furnished to any other Party without advance written approval from the Collaborating Party.

E.13. Financial Obligation. The continued performance of research by The Carl R. Darnall Army Medical Center under this Agreement is conditioned on the payment of funds to Carl R. Darnall Army Medical Center by the Collaborating Party as specified below. The Carl R. Darnall Army Medical Center will use the accounting procedures as required by applicable Army and Defense Finance and Accounting Service regulations for the handling of funds during the performance of the research. The Carl R. Darnall Army Medical Center shall not be obligated to perform any of the research specified herein or to take any other action required by this Agreement if the agreed-to funds are not transferred as required. The expiration/termination of this Agreement does not extinguish the obligation to pay any funds which have been earned by, or are due and owed at, the date of expiration/termination.

E.14. Payment Schedule. IRB Fees will be paid by the Collaborator to BAMC when approval is granted for this project.

E.15. Reimbursements. The Collaborating Party shall deposit funds in a distinct Department of the Army account under control of the Directorate of Resource Management, and managed by the Department of Clinical Investigation, BAMC. The deposit shall be made in the form of a check made payable to the "Treasurer of the United States" as follows:

E.16. Other Funds. Not applicable.

E.17. Accounting Records. When funds are provided to BAMC, it shall maintain distinct accounts, records, and other evidence supporting expenditures under this Agreement. BAMC shall provide the Collaborating Party an annual report accounting for the use of funds and a final fiscal report within four months after completing this Agreement or ending its research activities under this Agreement, if requested by the Collaborating Party. The financial accounts and records pertaining to this Agreement shall be available for reasonable inspection and copying by the Collaborating Party or its authorized representative(s).

E.18. The Payment Schedule is subject to modification by mutual consent of all Parties in the event unforeseen circumstances delay initiation of this project, including delays due to: insufficient volunteer enrollment, actions from responsible review or regulatory authorities, lack of equipment or malfunctions, or insufficient support personnel.

F. RESOURCES PROVIDED BY FEDERAL PARTIES.

G. REPORTS. **BAMC** agrees to report in a timely manner the results of any research conducted with the Resources to the Collaborating Party. **BAMC** agrees to provide all data supporting research results to the Collaborating Party.

H. BUSINESS ASSOCIATE AGREEMENT.

H.1. The Collaborating Party and any other party to this agreement are described for the purposes of this paragraph as business associates.

H.2. The business associates agree to comply with Public Law 104-191, Health Insurance Portability and Accountability Act (HIPAA), and all HIPAA regulations, to include DOD 6025.18-R, DOD Health Information Privacy Regulation, as well as **VHA HANDBOOK 1605.1**, to the extent applicable to business associates.

H.3. A business associate may not use or further disclose protected health information in a manner that would violate the obligations of a business associate under the above law and regulations, except that:

H.3.1. A business associate may use and disclose such information for the proper management and administration of the business associate; and

H.3.2. A business associate may provide data aggregation services relating to the healthcare operations of the Federal Parties.

H.4. A business associate shall:

H.4.1. Not use or further disclose protected health information other than as permitted or required by DOD regulation or as required by law.

H.4.2. Use appropriate safeguards to prevent use or disclosure of the information other than as allowed by DOD 6025.18-R.

H.4.3. Report to the Federal Parties any use or disclosure of the information not allowed by DOD 6025.18-R of which it becomes aware.

H.4.4. Ensure that any person or contractor to whom it provides protected health information received from, or created or received by the business associate on behalf of, the Federal

Parties, is subject to or agrees to the same restrictions and conditions that apply to the business associate with respect to such information.

H.4.5. Make available protected health information in accordance with Chapter 11, DOD 6025.18-R.

H.4.6. Make available protected health information for amendment and incorporate any amendments to protected health information in accordance with Chapter 12, DOD 6025.18-R.

H.4.7. Make available the information required to provide an accounting of disclosures in accordance with Chapter 13, DOD 6025.18-R.

H.4.8. Make its internal practices, books, and records relating to the use and disclosure of protected health information received from, or created or received by the business associate on behalf of, the Federal Parties, available to the Secretary of Health and Human Services for purposes of determining compliance with the HHS regulations; and

H.4.9. At termination of the function(s) for which the information is collected, if feasible, return or destroy all protected health information received from, or created or received by the business associate on behalf of, the Federal Parties, that the business associate still maintains in any form. In this case, the business associate shall retain no copies of such information. If such return or destruction is not feasible, maintain compliance with DOD 6025.18-R and limit further uses and disclosures to those purposes that make the return or destruction of the information not feasible. The business associate will document appropriately the action taken.

I. PRINCIPAL INVESTIGATOR.

I.1. The Principal Investigator may be assisted by others designated as Subinvestigators. Parties acknowledge that Texas A & M University and Computer Associates Inc. are not parties to this agreement, but may be consulted after the finalization of the SOW.

Sub-Investigators for this project are designated below:

Site Principal Investigator:
Michael L. Adams, Ph.D., LTC, Army, Psychologist, Behavioral Health Division
Carl R. Darnall Army Medical Center
Phone: (254) 286-7804

Cell Phone: (254) 535-4469
Beeper: (254) 903-2704
E-mail: michael.adams@amedd.army.mil

Brett Litz, Ph.D., Psychologist, Civilian
Associate Director, Behavioral Sciences Division, National Center for PTSD
VA Boston Health Care System
Phone: (857) 364-4131
E-mail: brett.litz@va.gov

Keith Young, Ph.D.
Pharmacologist, Civilian
Vice-Chair for Research
Department of Psychiatry and Behavioral Science
Texas A&M University HSC College of Medicine
Phone: (254) 743-0033
E-mail: kayoung@medicine.tamhsc.edu

Jed Goldart, M.D.
Consultant, Psychiatrist, Civilian
Computer Technology Associates, Inc.
Phone: 301-581-3266
E-mail: jgoldartmd@starpower.net

Tom Velez, Ph.D.
Chief Executive Officer
Computer Technology Associates, Inc
Phone: (301) 581-3266
E-mail: tom.velez@cta.com

Walter Penk, Ph.D.
Professor
Department of Psychiatry and Behavioral Science
Texas A&M University HSC College of Medicine
Phone: (830) 708-4338
E-mail: wepenk@gvtc.com

Kathryn Kotrla, M.D.
Chair, Department of Psychiatry and Behavioral Science
Texas A&M University HSC College of Medicine
Phone: (254) 724-3878
E-mail: kakotrla@swmail.sw.org

I.2. All notices required by this Agreement to be sent to the Principal Investigator will be sent to the following address:

Paul B. Hicks, M.D., Ph.D.
Associate Chief of Staff, Research
Central Texas Veterans Health Care System

1901 S. Veterans Memorial Dr. (151)
Temple, Texas 76504
(254) 743-2643